

REMARKS

In view of the foregoing amendments and the following representations, reconsideration and allowance of the above-identified application is respectfully requested.

On pages 2-3 of the Office Action the Examiner rejected claims 1, 4-17 and 20-24 under 35 USC 112, second paragraph.

Reconsideration is requested.

Claims 1 and 17 have been amended to more precisely point out and claim the present invention. Specifically, the recitation regarding the pH dependent materials has been moved from after the optional cosmetic coating to directly after the delayed release coating component recited as element (b)(i). No new matter has been added.

It is therefore requested that the above 112, second paragraph rejection be withdrawn.

On pages 3-10 of the Office Action, the Examiner rejected claims 1, 4-17 and 20-24 under 35 U.S.C. § 103(a) as being unpatentable over United States Patent No. 5,160,742 (hereinafter Mazer et al.) in view of United States Patent No. 6,372,255 (hereinafter "Saslowski") and United States Patent No. 5,478,577 (hereinafter "Sackler").

Claims 1 and 17 have been amended to recite that the core consists of a "binder that is water soluble and has a viscosity of greater than 50,000 mPa when tested in a 2% aqueous solution at 20°C", a diluent, and optionally a glidant and/or lubricant. Further, claims 1 and 17 have been amended to point out that the dosage form only contains on functional sustained release coating, namely a single delayed release coating. Additionally, claims 4-6 have been cancelled and claims 7-9 have been amended to correct for proper dependency. Support for these amendments can be found at least in the claims as originally

filed and in paragraphs 0035-0047 of the published application. No new matter has been added.

Mazer et al. discloses a dual (or triple) coated active containing core. *See* Examples 1- 16 of Mazer et al. Further, the dual (or triple) coated core disclosed in Mazer et al. does not contain a high viscosity binder as recited in the presently amended claims. Additionally, Mazer et al. is not directed towards dosage forms containing analgesic drugs, but does not teach the use of oxycodone. Further, the dosage forms disclosed in Mazer et al. do not contain an immediate release layer of oxycodone.

The inventors of the present invention have developed a novel sustained release dosage form for providing an efficient and effective release of oxycodone by employing a core containing oxycodone and a high viscosity binder surrounded by a single delayed release coating system which employs two pH dependent materials, and finally an immediate release layer of oxycodone. This novel formulation overcomes the necessity to use multiple delayed or sustained release coating systems as taught in the Mazer et al. patent.

Additionally, Applicants respectfully submit that the presently amended claims are patentable over Mazer et al. in combination with the Sackler and/or Saslawski references.

The present invention as recited in the pending claims is patentable over the Sackler and/or Saslawski references because the Applicants have surprisingly discovered a sustained release oxycodone formulation that provides safe therapeutic levels of oxycodone over a period of time using a unique combination of pH **dependent** coating materials in a single delayed release coating surrounding a core containing oxycodone and a high viscosity polymer. The cited references do not rely primarily upon pH dependent agents to control

the release of the active pharmaceutical dosage form. More importantly the cited references do not suggest the combination of two pH dependent agents that dissolve or degrade at separate and distinct pH values as required by the pending claims.

The Sackler reference discloses an opioid formulation designed to provide large peak to trough plasma concentrations of the opioid over a 24 hour time period. The dosage form described in the Sackler reference is designed to release the opioid at a rate that is **independent** of pH. *See* Col. 7, lines 46-48. This is the exact opposite to the pH dependent dosage form recited in the pending claims.

The Saslawski reference also fails to disclose or suggest a sustained release oxycodone dosage form that employs a unique pH dependent coating as recited in the pending claims. Saslawski disclose a multilayer tablet that comprises an immediate release layer and a sustained release layer. The sustained release layer disperses the active pharmaceutical ingredient in an inert polymeric matrix. *See* Col. 1, lines 57-67. The release of the active pharmaceutical ingredient is pH **independent**. *See* Col. 2, lines 38-31 (“The matrix of the second layer retains its physical and chemical integrity throughout the prolonged release of the active ingredient, regardless of the pH variations.”) and Col. 10, line 65 to Col. 11, line 1 (“On the other hand, these copolymers are absolutely inert in relation to the body, which ensures release of the active ingredient independently of the influence of the body (and in particular of pH variations)”).

In view of the clear teachings in both the Sackler and the Saslawski references to employ pH independent polymers to control the release of the drug from the disclosed dosage forms, Applicants respectfully submit that an individual of ordinary skill would not be lead to the develop a sustained release oxycodone dosage form which relies upon a

unique combination of only two pH dependent enteric agents to control the release of the oxycodone.

The cited prior art does not teach or suggest a core containing oxycodone with a high viscosity polymer surrounded by a single functional coating system containing two pH dependent materials as recited in the presently amended claims. Specifically, Mazer et al. requires the use of multiple sustained release coating systems and does not teach the use of oxycodone or an immediate release coating; Saslawski also does not teach the use of oxycodone, or delayed release coatings containing two pH dependent materials; and Sackler does not employ a delayed release coating containing two pH dependent materials. Therefore, it would require improper hindsight to pick and choose portions out from the cited prior art to arrive at the presently claimed invention. Moreover, one skilled in the art could not just apply the coating system from Mazer et al., but would need to use a modified version that only employed one coating layer, which is not disclosed in Mazer et al.

Based upon the foregoing amendments and representations, Applicants respectfully submit that the rejection of the claims in the above-identified application has been overcome and should be withdrawn. Early and favorable action is earnestly solicited.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'NP Chiara', with a stylized flourish at the end.

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